WHAT IS CLAIMED IS:

1. A method of cytologically evaluating epithelial cells collected from a human breast duct comprising:

providing a ductal fluid sample comprising ductal epithelial cells from a duct of a breast of a patient collected by ductal lavage;

evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

classifying the sample as being normal, atypical or malignant based on the observed indicia.

2. A method as in claim 1, wherein the sample is classified as malignant when the sample is characterized by at least some of a loss an identifying feature selected from the group consisting of cell cohesiveness, loose clusters of epithelial cells, enlarged cells, enlarged nuclei, high nuclear-to-cytoplasmic ratio, increased cytoplasm in some cells, irregular nuclear membranes, clumped chromatin, hyperchromatic chromatin, unevenly dispersed chromatin, enlarged nucleoli, multiple nucleoli, marked variation among the cells of the sample in cell size and nuclear size, necrotic debris, and microcalcifications in background material appearing as dense material with smooth borders and concentric layers or dystrophic and amorphous.

3. A method as in claim 1, wherein the sample is classified as atypical with marked changes when the sample is characterized by at least an identifying feature selected from the group consisting of enlarged ductal epithelial cells, marked nuclear increase in ductal epithelial cells, variation in size and shape of the ductal epithelial cells as compared to normal ductal epithelial cells, abundant cytoplasm in some cells, decreased nuclear-to-cytoplasmic ratios in some cells, coarse chromatin, mild abnormality in chromatin distribution, larger nucleoli than in normal cells, multiple

nucleoli, more prominent nucleoli, nuclei groups that appear to be overlapping, and mitotic figures.

4. A method as in claim 1, wherein the sample is classified as atypical with mild changes when the sample is characterized by at least some of an identifying feature selected from the group consisting of single ductal cells, cohesive multilayered cells, complex groups of cells, monolayered cells, an increased number of cell layers compared to normal cells, increased overlapping of the cells, nuclear crowding of cells, minimally enlarged cells, moderate increase in nuclear size to within a range from about 12 to about 16 μm in diameter, slight anisonucleosis in some cells, and presence of nucleoli.

5. A method as in claim 1, wherein the sample is classified as normal when the sample is characterized by at least some of an identifying feature selected from the group consisting of single cells, monolayer sheets, tight cells clusters usually one or two cell layers thick, small nuclei in a size range from about 8 to about 12 μm in diameter, high nuclear-to-cytoplasmic ratio depending on the orientation of the cells in clusters, in single cells a columnar shape of cytoplasm, in single cells discreet small vacuoles in the cytoplasm, in single cells discreet cytoplasmic border, cohesive groups of ductal epithelial cells with cells of uniform size and regular round to oval shape, monolayer sheets of cells with uniform, small cells, monolayer sheets of cells with small inconspicuous nucleoli.

6. A method as in claim 1, wherein the sample is classified as insufficient cells to make a diagnosis (ICMD) when the sample is characterized by less than 10 cells in the sample.

7. A method as in any of claims 1-6 wherein the ductal fluid is retrieved by placing a ductal access tool in the duct and infusing fluid into the duct through the tool and retrieving from the accessed duct through the tool a portion of the infused fluid mixed with ductal fluid.

8. A method as in any of claims 1-6 wherein the method is repeated for a plurality of ducts in a breast.

9. A method as in claim 1, wherein providing the ductal fluid sample comprises obtaining the sample from the breast.

10. A method as in claim 1, wherein providing the ductal fluid sample comprises receiving a sample which had been previously obtained.

11. A method as in claim 1, wherein the fluid infused is in a range from about 2 ml to about 100 ml during a total lavage procedure on a single breast duct.

12. A method as in claim 1, wherein the fluid sample retrieved is in a range from about 2ml to about 30 ml of wash fluid mixed with cellular material.

13. A method as in claim 1, wherein the cells retrieved comprise excess of about 500 cells.

14. A method as in claim 1. wherein the cells retrieved comprise an amount in a range from about 500 cells to about 40,000 cells from a single breast duct.

15. A method as in claim 1, wherein the sample retrieved comprises one or more clusters of cells, wherein a cluster comprises 10 or more ductal epithelial cells.

16. A method as in claim 1 further comprising:

examining the ductal fluid sample to determine the presence of a marker selected from the group consisting of a protein, a polypeptide, a peptide, a nucleic acid, a polynucleotide, an mRNA, a small organic molecule, a lipid, a fat, a glycoprotein, a glycopeptide, a carbohydrate, an oligosaccharide, a chromosomal abnormality, a whole cell having a marker molecule, a particle, a secreted molecule, an intracellular molecule, and a complex of a plurality of molecules

17. A system of cytological evaluation of epithelial cells collected from a human breast duct comprising:

a tool or apparatus for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct;

a chart or written guidelines for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

an algorithm for classifying the sample as being normal, atypical or malignant based on the observed indicia.

18. A system as in claim 17, wherein the tool or apparatus for accessing a breast duct comprises a breast duct access and fluid and cell retrieval tool, and one or more of a probe, a tool for administering anesthetic, marking tools for marking an accessed or fluid yielding duct, or a collection receptacle for collecting retrieved fluid and cells.

19. A system as in claim 17, wherein the algorithm classifies the sample as malignant when the sample is characterized by at least an identifying feature selected from the group consisting of a loss of cell cohesiveness, loose clusters of epithelial cells, enlarged cells, enlarged nuclei, high nuclear-to-cytoplasmic ratio, increased cytoplasm in some cells, irregular nuclear membranes, clumped chromatin, hyperchromatic chromatin, unevenly dispersed chromatin, enlarged nucleoli, multiple nucleoli, marked variation among the cells of the sample in cell size and nuclear size, necrotic debris, and microcalcifications in background material appearing as dense material with smooth borders and concentric layers or dystrophic and amorphous.

20. A system as in claim 17, wherein the algorithm classifies the sample as atypical with marked changes when the sample is characterized by at least an identifying feature selected from the group consisting of enlarged ductal epithelial cells, marked nuclear increase in ductal epithelial cells, variation in size and shape of the ductal epithelial cells as compared to normal ductal epithelial cells, abundant cytoplasm in some cells, decreased nuclear-to-cytoplasmic ratios in some cells, coarse chromatin, mild

abnormality in chromatin distribution, larger nucleoli than in normal cells, multiple nucleoli, more prominent nucleoli, groups of nuclei that appear to be overlapping, and mitotic figures.

21. A system as in claim 17, wherein the algorithm classifies the sample as atypical with mild changes when the sample is characterized by at least some of an identifying feature selected from the group consisting of single ductal cells, cohesive multilayered cells, complex groups of cells, monolayered cells, an increased number of cell layers compared to normal cells, increased overlapping of the cells, nuclear crowding of cells, minimally enlarged cells, moderate increase in nuclear size to within a range from about 12 to about 16 μm in diameter, slight anisonucleosis in some cells, and presence of nucleoli.

22. A system as in claim 17, wherein the algorithm classifies the sample as normal when the sample is characterized by at least some of an identifying feature selected from the group consisting of single cells, monolayer sheets, tight cells clusters usually one or two cell layers thick, small nuclei in a size range from about 8 to about 12 μm in diameter, high nuclear-to-cytoplasmic ratio depending on the orientation of the cells in clusters, in single cells a columnar shape of cytoplasm, in single cells discreet small vacuoles in the cytoplasm, in single cells discreet cytoplasmic border, cohesive groups of ductal epithelial cells with cells of uniform size and regular round to oval shape, monolayer sheets of cells with uniform, small cells, and monolayer sheets of cells with small inconspicuous nucleoli.

23. A system as in claim 17, wherein the algorithm classifies the sample as insufficient cells to make a diagnosis (ICMD) when the sample has fewer than 10 epithelial cells.

24. A method of cytologically evaluating epithelial cells collected from a human breast duct comprising:

providing a ductal fluid sample comprising at least 500 ductal epithelial cells from a duct of a breast of a patient;

evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size,

nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

classifying the sample as being normal, atypical or malignant based on the observed indicia.

25. A method of cytologically evaluating epithelial cells collected from a human breast duct comprising:

providing a ductal fluid sample comprising at least 100 ductal epithelial cells from a duct of a breast of a patient and at least one cell clump comprising at least 10 cells from the duct;

evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

classifying the sample as being normal, atypical or malignant based on the observed indicia.